Statement of Carl Dvorak
Epic Systems Corporation
before the
HIT Policy Committee Adoption/Certification Workgroup
Feb. 25, 2010

Thank you for the opportunity to share our experience and insights here today. My name is Carl Dvorak and I am executive vice president of Epic Systems Corporation, a manufacturer of software for medical groups and healthcare organizations.

My experience dates back to the early 1990s as a developer working with a small team of programmers to create Epic's first physician-oriented EHR.

Today I am responsible for our software development and support activities. I work closely with programmers, implementers and customers to develop software to help improve patient care.

The work that is done by Epic – and by our colleagues in the industry – is helping to modernize America's health care system. We can't afford to stay in the pad-and-pencil days. It's too costly and in many cases it's dangerous.

Epic's electronic health records are used to facilitate care for millions of citizens served by Federally Qualified Health Centers (FQHCs), county hospitals, community hospitals, independent medical groups and some of the largest integrated health systems and networks in the country.

We strive to create high quality healthcare software. We also install and support it directly with the organizations that use it.

While Epic software does not directly diagnose or treat patients, our systems are used in clinical settings where it's imperative that we deliver accurate and timely information to clinicians at the point of care. In other words, our systems help doctors, nurses and other health care providers do what they do best: treat patients.

We should remember also that computers are not new to healthcare. And, in particular, they are not new to the order entry and management process. Computer software has been used for over 30 years by pharmacists, lab technicians, nurses and many other healthcare providers to capture and manage orders.

What's changing with HITECH is the requirement for physicians to directly use the computer in an effort to even further improve accuracy related to orders. The goal is to further reduce errors related to legibility and ambiguity of the orders communicated via handwriting or verbally. The new opportunities

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for reminders and advisories at the point of physician ordering hold promise for even more significant safety improvements.

Ensuring that we provide a safe and reliable electronic health record relies on many internal processes.

I'd like to share our perspective on what processes and best practices we think are most important to ensure a safe and effective EHR.

There are five essential elements. I'll summarize each with a comment on outcomes and then offer a perspective on regulation.

First, it is important that the software function as intended to avoid safety issues.

The development and testing of software follows a defined series of steps. These steps include design review, programming, programming peer review, quality assurance testing at the unit and system levels and, in most cases, regression testing.

When this protocol is adhered to, our experience shows that in most use cases the software functions as intended.

As use cases become more exotic, more creativity and vigilance will be needed to ensure that we anticipate and test as many exotic use cases as possible.

When the software does not operate as intended, we initiate a formal review process that examines the failure, and learn from what went wrong. Then, if necessary, we change our processes or implement additional testing to prevent similar problems from occurring.

By adhering to these processes, our software operates as intended in the vast majority of use cases, including many exotic ones.

A second critical element is availability and real-time access to the electronic health record.

This access is now just as important, if not more so, than access to any paper medical record. The need for reliable systems is becoming critical, especially as more and more hospital ICUs and clinics rely on information about patients that is available only through computers.

There are a number of best practices the industry follows to ensure that multiple copies of the medical record exist and that there are multiple network paths available to access the data. Many systems, including ours, provide an in-hospital version of the record on a battery backed-up computer that can be available in the event of a catastrophic event.

These best practices, if implemented correctly, ensure that medical information is both available and accessible in a crisis.

The third critical element is user-friendly design – where science intersects with art and imagination.

Proper design is important to ensure that a care provider reaches the right conclusion when he or she reviews medical information on a computer screen.

Design has elements of science. Guidelines for consistency help users effectively navigate a system in a predictable manner. For example, a rule that consistently juxtaposes the location of the Accept Button with the Cancel Button helps providers avoid clicking Cancel when they intend to click Accept.

Also important:

- Guidelines for use of color – red for danger, yellow for caution or warning, green for good, blue underlined text that says "click on me".
- Guidelines that recognize that not all users see color the same way and that color alone may not be sufficient for all users; and
- Guidelines that encourage developers to use recognizable icons or other keys to ensure proper interpretation of such things as critically abnormal lab results.

We also shouldn't dismiss the importance of art and imagination in design. Consider where we'd be today if back a few years ago designers had decided that all cell phones should be consistent. Rules for cell phone consistency might have made innovative design changes such as the iPhone impossible.

Enhancing the science of design is important and helpful to our industry. The user interface and human factors engineers we employ recognize that much of that science can go a long way in helping to produce a safe and usable EHR.

There is no substitute for having development staff work shoulder-to-shoulder with doctors and nurses to understand how our programming will be used in practice. It's also important that programmers, user interface engineers, and quality assurance staff support new users going live on an EHR to ensure Epic staff understand how caregivers practice medicine and how organizations engineer their processes for comprehensive care.

We also incorporate clinicians directly into the development processes. Physicians and nurses on staff participate with initial design and final software reviews with developers and quality assurance staff.

That said, the policing of design by a third party or agency, however well intended, will likely stifle innovation and inhibit the growth and development of EHRs in the future. End users in the medical industry should remain the final judge on design.

A fourth element is the configuration and the technical implementation of an EHR.

Flexibility and configuration are required to accommodate different approaches to providing care. Health care organizations continue to innovate with new care models. They follow processes such as LEAN and Six Sigma to create more reliable and cost-effective care.

Each specific configuration or pattern of use of an EHR must be logical. And it must be appropriate. For example, if results are to be routed to a referring provider, there must be a screen upstream to record the name and address of the referring provider.

Software developers can help by designing guardrails to ensure that configurations are complete and make sense. For example, if you allow flexibility to route results according to a set of rules, it is important to ensure that if no rule applies, the result is still routed to someone who can recognize what to do with it.

Medical records often have to be integrated with existing software systems, content sources, and self-developed content. Those integrated solutions must be tested to ensure they work together.

Testing the final configuration of an EHR with all its software, workflow, third-party connections and content is absolutely critical for safety and success. Typical EHRs with support for inpatient, outpatient, specialty and home care allow for significant configuration and often require many connections to other health information technology systems.

Organizations must test their configuration carefully and continuously as they modify their care models to ensure correct and predictable operation. There is no set of comprehensive guardrails that we've identified that would ever eliminate this need.

The fifth and final safety-related element is training.

Training is an often overlooked and undervalued area.

Training need not consume many days or weeks, especially if an EHR is designed well. But training cannot and should not be omitted. We strongly recommend that our customers not give out passwords to access the EHR unless providers have been trained.   We also recommend they ask providers to take a proficiency test to ensure that they understand how to use the EHR appropriately.

"*Charting etiquette*" is a term coined early in one of our large multi-specialty group practice installations. The consistent use of an EHR is important when many caregivers share a common record. Orders should be placed in the order entry section of the chart and medications added to the medication list. Information needs to be recorded in the standard places in an electronic record, not put in a note in the hope that the next nurse or a doctor will notice it.

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It takes the better part of a decade to complete a medical education, yet providers often avoid two hours of e-learning and a day in the classroom. Training is an investment that is critical to ensure the safe and effective use of an EHR.

I also want to take a moment to comment on the importance of managing a process that ensures that every reported potential or observed safety concern is effectively dealt with in a transparent manner. Epic was a leader in creating the draft EHRA safety process. We strongly support that approach and maintain careful internal controls and a process and a philosophy that any safety concern, no matter how small or unlikely, is quickly and carefully communicated with all users of our EHR with appropriate assistance to manage any necessary mitigation.

You also asked about an industry perspective on regulation. We do not currently create any products that are regulated and do not have experience in this area. I did, however, ask two long-time users of our EHR for their insights.

They both expressed concerns about one highly regulated area: blood banks. As they see it, blood bank software has not kept pace with their needs due to the regulatory processes imposed on their vendors. They also cited regulatory delays in receiving corrections to known safety issues. They both observed that the effort to regulate blood banks did not make the software any safer. They also felt it slowed innovation, and complicated getting necessary fixes without any measurable benefit as compared with their experience with electronic health records.

My final comment today is on outcomes.

In the 20 years I've worked on medical software at Epic, I've heard many stories of lives saved, health status improved, and the elimination of many mistakes endemic to paper record keeping.

Developing EHRs with current industry standard best practices for design, development and support, coupled with open, honest and transparent communication with our customers provides an EHR that can support important improvements in the delivery of safe and effective care. Regulation will not necessarily create a safer EHR and might actually limit innovation and responsiveness when it is needed most.

We should proceed thoughtfully when discussing regulation of EHRs. We at Epic hope than any decisions made regarding regulation are decisions based on actual outcomes and not on politics.

Thank you for your consideration.